UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,276	10/20/2003	Daniel Cimbora	1834.01	8598

26698 7590 11/27/2006

MYRIAD GENETICS INC.
INTELLECUTAL PROPERTY DEPARTMENT
320 WAKARA WAY
SALT LAKE CITY, UT 84108

EXAMINER	
MOORE, WILLIAM W	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/690,276	CIMBORA ET AL.	
	Examiner	Art Unit	
	William W. Moore	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-37* is/are pending in the application.

4a) Of the above claim(s) *29-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's amendment to claim 21, providing sequence identifiers for both PRAK and ERK3 kinases that form an isolated protein complex, and amendments to the Title of the application and the statement of continuing data at page 1 of the specification to provide an alternative date format and to correct an error in designating a priority application in the Response filed 12 September 2006 have been entered. The further amendments to the specification in the Response providing a statement referring to the sequence listing at page 2 therein, and replacing Table 1 at page 18 therein with a table that includes sequence identifiers for the PRAK and ERK3 kinases have also been entered. These amendments overcome the objections of record to the specification and the rejection of record of claims herein under the second paragraph of 35 U.S.C. § 112 stated in the communication mailed 12 May 2006. Claims 21-37 remain in the application of which claims 29-37 are withdrawn from consideration as drawn to a non-elected invention pursuant to Applicant's provisional election of product claims 21-37 for prosecution in the Response filed 6 February 2006.

Priority

Applicant's comments at pages 8 and 9 addressing the issue of priority for the formation of a complex between the PRAK and ERK3 kinases have been considered. As noted at page 2 of communication mailed 12 May 2006, the disclosure of Table 1 herein is accorded priority to the disclosure in Example 10 at page 29 of US provisional application No. 60/168,377 filed 2 December 1999 and the corresponding disclosure of Table 38 of application serial No. 09/727,384, filed 1 December 2000. Both disclose the formation of an *in vitro* complex of the integral amino acid regions of PRAK and ERK3 kinases represented in Table 1 at page 18 herein. While the text of the provisional application No. 60/168,377 that Applicant cites discloses no particular processes for the

isolation of either a recombinantly-expressed PRAK kinase or ERK3 kinase, a sentence spanning pages 20-21 of the earliest priority document proposes that either component can be purified, or isolated, "by conventional biochemical and immunological methods", and this general reference is considered to enable the isolation of either component of a claimed complex after they are recombinantly expressed in separate host cells. The critical conditions stated at pages 200-201 of the instant application allowing detection of the formation of an **isolated**, i.e., an *in vitro*, PRAK-ERK3 complex are not provided by either the December 1999-filed provisional application or the December 2000-filed utility application: Example 10 of the 2 December 1999-filed provisional application No. 60/168,377 indicates formation of an *in vivo* PRAK-ERK3 complex but Examples 32-34 at pages 33-36 of the provisional application disclose no isolation of individual PRAK kinase or ERK3 kinase components to form an isolated complex or any conditions for formation of an isolated, *in vitro*, PRAK-ERK3 complex. Example 12, the discussion at page 20, Table 38, and Examples 33-35 at pages 42-44 of application serial No. 09/727,384 likewise disclose no isolation of a PRAK-ERK3 complex from transformed yeast host cells or formation of an isolated, *in vitro*, PRAK-ERK3 complex by contacting a PRAK component with an ERK3 component under conditions permitting a binding interaction between these two molecular components. Thus a claimed, isolated, PRAK-ERK3 complex has the priority of the 18 July 2003 filing date of the instant application.

Double Patenting

Applicant's assistance is acknowledged in identifying copending application serial No. 10/267,476 as an application wherein one or more claims implicate a complex that comprises a kinase. The USPTO's scanned application database is the basis for the rejection of record of claims herein over claims of the copending serial No. 10/267,476.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Applicant states no particular argument in the Response filed 12 September 2006 traversing the provisional rejections of record of claims herein for obviousness-type double patenting but notes in the paragraph spanning pages 12 and 13 of the Response that the "grounds for [the rejections of record] stem from the Examiner's concern that the interacting proteins of the instant invention . . . are both kinases, and could conceivable share primary structure . . . with other kinases." As noted in the preface to the rejections of record for obviousness-type double patenting in the communication mailed 12 May 2006, the rejections of record are required not only because claims 21, 23, 24, 27 and 28 lack descriptions of a particular structure for a PRAK or ERK3 kinase involved in an "interaction" where claims 21, 23, 24, 27 and 28 do not require that a kinase, or a fragment of a kinase, share substantial structural relationship to a particular amino acid sequence region of either of SEQ IDs NOs:730 or 732, and state no lower limit on the size of a "fragment"; the rejections of record are also required in view of the non-structural definition of "interaction" at page 11 of the specification that embraces a, "state of proximity between [ ] interaction domains, fragments, proteins or entities [that] may be transient or permanent, reversible or irreversible, [so long as] it is in contrast to and distinguishable from contact caused by natural random movement of two entities [where t]ypically, although not necessarily, an 'interaction' is exhibited by the binding

between the interaction domains, fragments, proteins, or entities [and e]xamples of interactions include specific interactions between antigen and antibody, ligand and receptor, enzyme and substrate, and the like". The rejections of record recognize this broad definition of kinase interaction because many kinases disclosed in the art have, as do PRAK and ERK3, multiple cellular partners for interaction including other kinases. Since neither a particular structure nor a particular interaction are required in the complexes of pending claims 21, 23, 24, 27 and 28 rejected herein, unlike specific PRAK and ERK3 fragments of claims 25 and 26 not subject to the following rejections, and claims of the copending applications describe complexes comprising at least one kinase, three of the provisional obviousness-type double patenting rejections of record are maintained because the conflicting claims have not in fact been patented.

Claims 21, 23, 24, 27 and 28 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/035,344. Although the conflicting claims are not identical, they are not patentably distinct from each other because a complex of the pending claims comprising a structurally undefined "fragment" of PRAK and a structurally undefined "fragment" of ERK3 are indistinguishable from a complex comprising similarly structurally undefined fragments of a kinase of a complex of the co-pending claim, where a "fragment" of either the instant application or the co-pending application may be involved in a kinase interaction and where fusion proteins of claims 23, 24, 27 and 28 herein are also proteins of claim 21 herein and any such fusion protein may include any portions of proteins comprised by the complexes of the co-pending claims.

Claims 21, 23, 24, 27 and 28 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/194,385. Although the conflicting claims are not identical, they are not patentably distinct from each other because a complex of the pending claims comprising a structurally undefined "fragment" of PRAK and a structurally undefined "fragment" of ERK3 are indistinguishable from a complex comprising similarly structurally undefined fragments of a kinase of a complex of the co-pending claims, where a "fragment" of either the instant application or the co-pending application may be involved in a kinase interaction and where fusion proteins of claims

23, 24, 27 and 28 herein are also proteins of claim 21 herein and any such fusion protein may include any portions of proteins comprised by the complexes of the co-pending claims.

Claims 21, 23, 24, 27 and 28 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21 and 30 of copending Application No. 10/267,476. Although the conflicting claims are not identical, they are not patentably distinct from each other because a complex of the pending claims comprising a structurally undefined "fragment" of PRAK and a structurally undefined "fragment" of ERK3 are indistinguishable from a complex comprising similarly structurally undefined fragments of a kinase of a complex of the co-pending claims, where a "fragment" of either the instant application or the co-pending application may be involved in a kinase interaction and where fusion proteins of claims 23, 24, 27 and 28 herein are also proteins of claim 21 herein and any such fusion protein may include any portions of proteins comprised by the complexes of the co-pending claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-28 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's arguments at pages 13-21 in the Response filed 12 September 2006 have been fully considered but they are not persuasive. It is agreed that this rejection does not affect complexes of proteins that comprise the specific, integral, regions of the PRAK and ERK3 kinases described by Table I of the specification. The arguments of the Response suggest that the rejection of record of claims 21-28 is contrary to the set of considerations in Example 14 of the USPTO Written Description Training Materials. Example 14 of these Training Materials concerns a claim to a polypeptide having a particular function recited in the claim and disclosed in the specification and sharing at

least 95% structural identity to an integral polypeptide disclosed in the specification and identified by a sequence identifier. By comparison, the claims rejected herein are drawn to isolated complexes comprising members of two broad genera of kinase fragments and variants having no particular assayable characteristics, formed under no particular conditions, while the specification provides a written description of only one isolated complex formed under conditions set forth at page 200 of the specification by a specific fragment of a specific PRAK kinase and a specific fragment of a specific ERK3 kinase. Claims 26 and 27 are the pending claims that come closest to the claim in the Written Description Training Materials' Example 14, but each requires just one component of a claimed complex to have a particular degree of identity to a particular region of either PRAK or ERK3, embracing, respectively, PRAK variants comprising as many as 37 amino acid sequence alterations at undisclosed locations and undisclosed nature, and ERK3 variants comprising as many as 93 amino acid sequence alterations at undisclosed locations and undisclosed nature, in any combination or pattern throughout the PRAK and ERK3 fragments. Unlike the set of facts provided in Example 14 of the Written Description Training Materials, none of the rejected claims requires that either a divergent PRAK or a divergent ERK3 have a particular activity that is amenable to an assay for that activity disclosed in the specification. Like the claims to which it pertains, this argument is wide of the mark.

The Response also argues that the rejected claims meet the legal standard set by recent Federal Circuit decision in Invitrogen Corp. v. Clontech Laboratories, Inc., 429 F.3d 1052 (Fed. Cir. 2005) cited by Applicant at page 17 of the response. The patent claim affirmed by the appellate panel required, however, that a modified product have characteristics that could be determined by two separate assays disclosed in the patent specification, which also disclosed a particular structural alteration, the deletion of one domain, of a reverse transcriptase that will produce the characteristics recited in the

patented claim, as well as structural modifications that would stabilize a modified product of the patent claim. The patent specification supporting the claim disclosed that each assayable activity resided in a physically separate domain of this bifunctional enzyme, thus the assays were adequate even after the structural modification because the modification reducing one activity according to the patent claim did not substantially affect the other activity recited in the patent claim. The instant specification and claims, by comparison, provide no guidance as to where to make any structural changes, or the nature of the changes that might be made, anywhere, in any combination or pattern, throughout the amino acid sequences of the specific, integral, PRAK and ERK3 kinase fragments indicated in Table 1 at page 18 that will provide products the activity of which can be assayed according to the specification. The specification likewise fails to disclose common structural attributes of either component with which the artisan can identify other members of either genus of divergent components of the instant claims 21-28, thereby recognizing Applicant's possession thereof at the time the invention was made. Nonetheless, amending claim 21 to comport with Example 14 of the Written Description Training Materials in order that it describe (i) full-length PRAK and ERK3 components having the amino acid sequences set forth in, respectively, SEQ IDs NOs:730 and 732, (ii) specific fragments of PRAK and ERK3 components that the specification discloses, (iii) variants of the full length PRAK and ERK3 components having amino acid sequences sharing at least 95% sequence identity to, respectively, SEQ IDs NOs:730 and 732 coupled with an assay disclosed in the specification that will identify functional variants, and (iv) fusion proteins that comprise the components of (i) through (iii), will overcome this rejection of record, which is maintained unless and until such amendment is made.

Claims 21-28 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while enabling for the *in vivo* and *in vitro* preparation of an isolated protein complex comprising (i) full-length PRAK and ERK3 components having the amino acid sequences set forth in, respectively, SEQ IDs NOs:730 and 732, (ii) specific fragments

of PRAK and ERK3 components that the specification discloses, (iii) variants of the full length PRAK and ERK3 components having amino acid sequences sharing at least 95% sequence identity to, respectively, SEQ IDs NOs:730 and 732 coupled with an assay disclosed in the specification that will identify functional variants, and (iv) fusion proteins that comprise the components of (i) through (iii), as well as enabling the use of such a complex in purifying a native PRAK kinase, does not reasonably provide enablement for preparation of an isolated complex of undisclosed fragments or variants of a native PRAK kinase or a native ERK3 kinase or the use thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments at pages 21-25 in the Response filed 12 September 2006 have been fully considered but they are not persuasive. This rejection does not affect proteins that comprise the specific, integral, regions of the PRAK and ERK3 kinases described by Table I of the specification. The Response suggests that the specification enables formation of an **isolated**, detectable, complex under any conditions as a result of any possible interaction between two components where either component is an unspecified fragment of either SEQ ID NO:730 or SEQ ID NO:732, or is an undisclosed variant of either of SEQ IDs NOs:730 or 732 that diverges at as much 25% of the amino acid sequence positions of either of SEQ IDs NOs:730 or 732 or diverges at as much 25% of the amino acid sequence positions of any of the smaller, undisclosed, fragments of SEQ IDs NOs:730 or 732. Yet the only conditions taught in specification, at page 200, that permit detection of an **isolated** complex of PRAK and ERK3 components enable only detection of specific, not generic, components. While pages 61-64, 67-69, 98 and 197-201 of the specification teach that fusion polypeptides comprising specific fragments of otherwise unmodified mammalian PRAK and ERK3 kinases interact within yeast cells to generate a phenotype detectable in yeast cells, clauses (i) and (1) of claim 21 permit the rejected claims 21, 23, 24, and 28, taken in light of clauses (ii) and (2) of claim 1, to read on isolated complexes formed by fragments having just four amino acids of either PRAK or ERK3 where one amino acid, 25% of each fragment, may differ from a tetrapeptide region of SEQ ID NO:730 or SEQ ID NO:732 because the definition of "interact" in the specification requires no particular, assayable interaction.

The specification fails to offer the guidance of Schumacher et al., cited at page 23 of the Response and supplied with Applicant's Information Disclosure Statement, and Schumacher et al. made no homologues other than truncation variants, none of which were of a size approaching the extremely small fragments reached by the claims rejected herein. The rejection of record is therefore sustained where neither the prior art made of record herein nor Applicant's specification can identify, taken together, the myriad combinations of amino acids in the amino acid sequences of the two disclosed kinase fragments that might be altered, nor teach the nature of alterations that may be made, to permit polypeptides or peptides of the rejected claims to "interact" to form an isolated complex, or remain useful as a kinase, the basis for finding statutory utility in at least a disclosed PRAK, or ERK3, fragment within the very broad genera of the claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr Bragdon, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to

the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
20 November 2006

NASHAAT T. NASHED PHD.
PRIMARY EXAMINER